UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte HISASHI KASHIMA, HARUNOBU KUDO, and RYOH SUGIHARA

Appeal 2007-1627
Application 09/870,009
Technology Center 1600

Decided: October 29, 2007

Before ERIC B. GRIMES, LORA M. GREEN, and NANCY J. LINCK, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to DNA containing "watermark" sequences. The Examiner has rejected the claims as anticipated, indefinite, containing new matter, and encompassing naturally occurring materials. We have jurisdiction under 35 U.S.C. § 6(b). We reverse the anticipation and new matter rejections, but affirm the rejections for indefiniteness and for encompassing naturally occurring materials.

BACKGROUND

The Specification discloses a method in which

> a nucleotide sequence carrying predetermined information, such as ID information, is embedded in DNA, so that DNA including such a nucleotide sequence is distinguishable. Thereafter, the nucleotide sequence carrying this predetermined information is called a watermark sequence. . . . When this watermark sequence is embedded in DNA including a value-added gene that is provided by selective breeding or through gene manipulation, . . . if the watermark sequence is detected in the DNA of a predetermined organism, it can be ascertained that the gene of the organism is a copy of the DNA wherein the watermark was previously embedded.

(Specification 11.)

DISCUSSION

1. CLAIMS

Claims 5, 8-12, 15, 17-27, and 30-34 are pending and on appeal.

Claims 5, 8, and 32 are representative and read as follows:

5. DNA having embedded information, comprising:
a gene portion including a predetermined gene;
a portion which is other than said gene portion; and
a nucleotide sequence which is not naturally occurring in said DNA and which is embedded in said portion which is other than said gene portion, and comprises source identification information which identifies a source of said predetermined gene in said gene portion.

8. DNA comprising:
at least one special sequence which is not naturally occurring in said DNA and that is intentionally designed and is included as a part of a nucleotide sequence,
wherein said at least one special sequence comprises source identification information which identifies the source of a predetermined gene which is included in a gene portion of said DNA, and

wherein said at least one special sequence is embedded in said DNA.

32. The DNA according to claim 5, wherein said portion which is other than said gene portion comprises a portion of said DNA which does not store a protein code sequence and transcription control information for said sequence.

2. NEW MATTER

Claim 32 stands rejected under 35 U.S.C. § 112, first paragraph, on the basis that it contains new matter. The Examiner reasons that "[w]hile the original claim 1 recites 'portion of said DNA other than a gene', there is a lack of written support for the limitation that the 'other portion' NOT include a protein code sequence and transcription control information" (Answer 5). That is, "[w]hile the specification discloses what . . . the 'gene portion' includes, this disclosure fails to teach what the 'other' portion does NOT include" (*id.*).

Appellants argue that "the Application defines a gene portion (e.g., in an exemplary aspect) as a portion where a protein code sequence and its transcription control information are stored. Thus, one of ordinary skill in the art would likely assume *and it is reasonable to conclude that* a portion other than a gene portion is a portion '*which does not store a protein code sequence and transcription control information for said sequence*', as recited in claim 32" (Appeal Br. 7).

We agree with Appellants that the Specification provides an adequate basis for the limitation at issue. The Specification states that a gene portion is (or can be) a region where "a protein code sequence and its transcription control information are stored" (Specification 13: 4-5). Claim 32 states that

the "other than said gene portion" recited in claim 5 does not include the protein coding sequence or transcription control information that the Specification defines as characteristics of a gene portion. The rejection of claim 32 under 35 U.S.C. § 112, first paragraph, is reversed.

3. INDEFINITENESS

Claims 8-10 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite, because "the phrase 'intentionally designed' . . . is vague and indefinite. It is unclear what limitation of a nucleic acid or structure is intended by the recitation that it be 'intentionally designed.'" (Answer 6.)

We agree with the Examiner that claims 8-10 are indefinite because it is unclear how the phrase "intentionally designed" limits the scope of the claims. Claim 8 recites a "special sequence that is not naturally occurring . . . and is intentionally designed." The Specification states that a "special sequence . . . is intentionally designed" (page 7) but does not disclose any structural features that distinguish an intentionally designed special sequence from other sequences of DNA.

"A claim is indefinite if its legal scope is not clear enough that a person of ordinary skill in the art could determine whether a particular composition infringes or not." *Geneva Pharms. v. GlaxoSmithKline*, 349 F.3d 1373, 1384 (Fed. Cir. 2003). Here, Appellants have not described the structural feature(s) that distinguish DNA that includes an intentionally designed sequence from other DNA. The scope of the claims is therefore ambiguous, and "ambiguity in claim scope is at the heart of the definiteness requirement of 35 U.S.C. § 112, ¶ 2." *Amgen, Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1342 (Fed. Cir. 2003).

Appellants argue that "one of ordinary skill in the art would likely consider the term '*not naturally occurring in said DNA and that is intentionally designed*' to mean a sequence which may be *intentionally designed by man*, as opposed to a naturally-occurring sequence in DNA (e.g., a sequence that is designed without any human intervention)." (Appeal Br. 9.)

Appellants' argument does not clarify what structural limitation is conferred on the claimed DNA by virtue of its comprising an "intentionally designed" DNA sequence. We conclude that the scope of claims 8-10, when read in light of the Specification, is indefinite. We therefore affirm the rejection of claims 8-10 under 35 U.S.C. § 112, second paragraph.

4. NONSTATUTORY SUBJECT MATTER

Claims 5, 8-12, 15, 17-27, and 30-34 stand rejected under 35 U.S.C. § 101 on the basis that the claims encompass naturally occurring humans and animals, and therefore are directed to nonstatutory subject matter (Answer 4). The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii).

The Examiner finds that the claims are directed to nonstatutory subject matter because "they encompass viral genomes comprising LTRs (long terminal repeats). In addition, any animal or person infected with such a virus inherently encompasses the LTRs, thus the cells recited in the instant claims encompass humans and animals." (Answer 4.)

We agree with the Examiner that claim 5 reads on naturally occurring DNA. Darnell[1] provides a diagram of a retrovirus integrated into cellular DNA (Darnell 973, Figure 24-13). The retroviral DNA includes a gene portion (the *gag*, *pol*, and *env* genes) and a portion other than the gene portion (the long terminal repeat (LTR)). All of the viral sequences are "not naturally occurring" in the chromosomal DNA of the virus-infected host.

Thus, the cellular chromosomal DNA with integrated provirus comprises a

- "gene portion including a predetermined gene" (the viral *gag*, *pol*, and/or *env* gene);
- a "portion which is other than said gene portion" (the LTR); and
- a "nucleotide sequence which is not naturally occurring in said DNA which is embedded in said portion which is other than said gene portion" (any of the viral LTR sequence).

Finally, the embedded viral sequence "comprises source identification information which identifies a source of said predetermined gene in said gene portion." That is, the viral LTR sequences are different from the host chromosomal sequence and differ from one retrovirus to another. Thus, for example, an integrated HIV provirus comprises LTR sequences that identify the source of the rest of the proviral DNA (including the *gag*, *pol*, and *env* genes) as the human immunodeficiency virus. We agree with the Examiner that claim 5 reads on a retrovirus integrated into a host cell's genomic DNA, and therefore encompasses nonstatutory subject matter.

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[1] Darnell et al., "Molecular Cell Biology," 2nd edition, Scientific American Books, 1990, pp. 971-975 (copy attached).

Appellants argue that the "nucleotide sequence added to a portion of DNA is *not just any old nucleotide sequence*, but instead is a nucleotide sequence that is '*not naturally occurring*'" (Reply Br. 2). As discussed above, however, viral DNA is not naturally occurring in a host cell's chromosomal DNA; "naturally occurring" human DNA, for example, does not include the HIV *gag*, *pol*, and *env* genes.

Appellants argue, however, that the claim language requires human intervention:

> [T]he nucleotide sequence *includes ["]source identification information*". . . . Appellant submits that this certainly implies some human intervention. That is, without human intervention the ["]source" of any genetic information in a gene portion is not an issue.
>
> Further, the source identification information "identifies" a source of the genetic information in the gene portion. Appellant again submits that this implies some human intervention. That is, the source identification information is not likely intended for identifying genetic information *without at least some human intervention* . . . .
>
> Further, claim 5 defines DNA having a *nucleotide sequence which is "embedded in" a portion of the DNA*. . . . [T]he claimed DNA in which a nucleotide sequence has been embedded *inherently requires human intervention* and is by definition not naturally-occurring.

(Reply Br. 2-3.)

We disagree with Appellants' interpretation of the claim language. As shown by Darnell, DNAs have "sources" and sequences that identify those sources even without human intervention. Darnell also shows that DNAs from different sources (e.g., human and viral) can be mixed, and one

"embedded" in the other, without human intervention. In addition, all DNA sequences inherently have subsequences "embedded" in them, in the sense that each subsequence is surrounded by (embedded in) the larger sequence of the entire DNA molecule.

We find that claim 5 reads on naturally occurring DNA and therefore encompasses nonstatutory subject matter. The rejection of claim 5 under 35 U.S.C. § 101 is affirmed. Claims 8-12, 15, 17-27, and 30-34 fall with claim 5.

5. ANTICIPATION

Claims 5, 8-12, 15, 17-27, and 30-34 stand rejected under 35 U.S.C. § 102(b) as anticipated by Lizardi.[2] Claims 5, 8-11, 15, 17-27, 30, and 34 stand rejected under 35 U.S.C. § 102(b) as anticipated by Arnot.[3] Since the Examiner relies on similar reasoning with respect to both rejections, we will consider them together.

The Examiner points to Lizardi's description of detecting mutations in the Huntington's chorea gene using an open-circle probe, and reasons that when the open-circle probe hybridizes to the genomic Huntington's chorea gene, the resulting complex meets all the limitations of claim 5:

> Figure 1 shows a open circle probe hybridized to a target sequence, and Figure 5 shows an open circle probe with detection tags which represents a first gene portion including a predetermined gene for Huntington's chorea, a second portion which is other than said gene portion (=probe), and a not naturally occurring nucleotide sequence (=detection tag) which

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[2] Lizardi, US 5,854,033, issued Dec. 29, 1998.

[3] Arnot et al., "Digital codes from hypervariable tandemly repeated DNA sequences in the *Plasmodium falciparum* circumsporozoite gene can genetically barcode isolates," Molecular and Biochemical Parasitology, Vol. 61, pp. 15-24 (1993).

> is embedded in a portion other than said gene portion and comprises source identification information of said predetermined gene.

(Answer 7.)

Similarly, the Examiner reasons that Arnot discloses

> genomic DNA including the CS gene of Plasmodium falciparum . . . which represents DNA including a predetermined gene, . . . along with the 5' flanking region wherein the flanking region represents a portion which is other than the gene portion. . . . Figure 1 shows two types of tandem repeat primers with TAG sequences bound to the genomic sequence. . . . [T]he primers represent not naturally occurring nucleotide sequences and the flanking primer represents a sequence embedded in portion other than said gene portion which identifies source of predetermined gene.

(*Id.* at 9-10.)

Appellants argue that "nowhere does Lizardi teach or suggest DNA that includes the gene for Huntington's chorea and the OCP [open-circle probe]. Instead, Lizardi teaches that the OCP may be used to replicate a target sequence *to detect a gene for Huntington's chorea in a sample mixture*" (Appeal Br. 13). With regard to Arnot, Appellants argue that "Arnot does not teach or suggest a nucleotide sequence which is not naturally occurring in said DNA and *which is embedded in said portion which is other than said gene portion*, and comprises source identification information which identifies a source of said predetermined gene in said gene portion" (*id.* at 27).

We agree with Appellants that the Examiner has not adequately shown that either Lizardi or Arnot teaches all of the limitations of the claims. Claim 5, for example, is directed to DNA that comprises a gene

portion, a non-gene portion, and a non-naturally occurring sequence embedded in the non-gene portion. DNA is a chemical compound. The claims' recital of DNA comprising a gene portion and a non-gene portion indicates that the recited portions are parts of the same DNA molecule.

By contrast, the Examiner has at best established that Lizardi and Arnot disclose hybridization complexes in which a gene and a non-naturally occurring sequence are present on separate DNA molecules. Hybridization of a probe to its genomic target does not make the probe and the genomic target parts of the same DNA molecule. Nor does hybridizing a probe to its target "embed" the probe sequence into the target DNA, in the usual sense of merging two separate molecules into a single molecule. The probe DNA and target DNA are separate DNAs even if they are hybridized to each other under appropriate conditions.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987). The Examiner has not established that Lizardi or Arnot disclose DNA comprising all of the limitations of the claims on appeal. The rejection of claims 5, 8-12, 15, 17-27, and 30-34 under 35 U.S.C. § 102(b) as anticipated by Lizardi, and the rejection of claims 5, 8-11, 15, 17-27, 30, and 34 under 35 U.S.C. § 102(b) as anticipated by Arnot, are reversed.

SUMMARY

We affirm the rejection of claims 8-10 under 35 U.S.C. § 112, second paragraph, and the rejection of claims 5, 8-12, 15, 17-27, and 30-34 under 35

U.S.C. § 101. We reverse the rejection of claim 32 under 35 U.S.C. § 112, first paragraph, and the rejections under 35 U.S.C. § 102(b).

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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